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April 29, 2005

## VIA HAND DELIVERY

Division of Dockets Management Branch  
U.S. Food and Drug Administration  
Department of Health & Human Services, rm. 1-23  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

### PETITION FOR STAY OF ACTION

Docket No. 2003P-0159

The undersigned, on behalf of Wyeth Pharmaceuticals ("Wyeth"), submits this petition requesting that the Commissioner of Food and Drugs stay the effective date of the following action.

#### *A. Decision involved*

By letter of March 30, 2005,<sup>1</sup> FDA approved Lachman Consultant Services, Inc.'s Suitability Petition, submitted April 16, 2003 (2003P-0159(CP1)) (the "Suitability Petition"). FDA's decision permits the filing of an abbreviated new drug application (ANDA) for venlafaxine hydrochloride extended-release tablets, 37.5 mg, 75 mg, and 150 mg. Wyeth has filed a petition for administrative reconsideration to this docket concurrently with this submission (the "Petition for Reconsideration").

#### *B. Action requested*

Pursuant to FDA's regulations at 21 C.F.R. § 10.35, the undersigned requests that the Commissioner stay approval of the Suitability Petition until such time as the Commissioner has ruled on Wyeth's Petition for Reconsideration.

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<sup>1</sup> Letter from FDA to Lachman Consultant Services, Inc. (2003P-0159(PAV1)), at 1 (March 30, 2005)

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*C. Statement of Grounds*

Wyeth bases this Petition for Stay of Action on the grounds set forth in the Petition for Reconsideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Scott L. Cunningham", is written over a horizontal line.

Michael S. Labson

Scott L. Cunningham

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